REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

The foregoing amends claims 42-44 and 46 to depend from new claim 56, cancels claim 45, and adds new claims 56-65. These amendments are made without prejudice or disclaimer, and Applicant reserves the right to pursue any canceled subject matter in one or more applications with the same rights of priority as the instant application. Support for the added claims is found throughout the application as filed, such as in paragraph **[0159]** at page 26. Applicant therefore respectfully requests entry of these amendments, and reconsideration of claims 36-44 and 46-65.

Claim Objections

The claims were objected to for including two different claims numbered 44. Applicant notes that the Examiner renumbered claims 36-55 as claims 36-56, and the current listing of claims reflects that renumbering.

§103 Rejections

Claims 36-55 were rejected for alleged obviousness in view of Sunshine (U.S. Patent No. 5,100,918) and Knight (U.S. Patent No. 3,306,252). Applicant respectfully traverses this rejection.

Sunshine is alleged to teach a topical, ibuprofen-containing composition that also may comprise ethanol and that can be combined with sun-protective agents, such as sunscreens that contain PABA ester. Knight is alleged to teach a shielded aerosol medicament dispenser. This combination of references fails to teach or suggest the present invention for at least the reasons detailed below.

As recited in the instant claims, the apparatuses of the present invention include a container that holds a non-occlusive percutaneous or non-occlusive transdermal drug delivery system, itself comprising a therapeutically effective amount of at least one physiologically

active agent or prodrug, at least one dermal penetration enhancer, and at least one volatile liquid. As recited in the claims, "after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry within three minutes of application." There is no suggestion in the cited references of an apparatus containing such a composition.

Although Sunshine is alleged to teach a composition according to the invention, there is no teaching or suggestion in Sunshine of a composition formulated such that, after application to a dermal surface or mucosal membrane, the area becomes touch-dry within three minutes of application. Indeed, the Office Action does not even mention this aspect of the claimed invention or allege it to be taught or suggested by the cited references.

Sunshine is directed to topical compositions comprising ibuprofen for the treatment or prevention of UV radiation induced erythema (*e.g.*, sunburn). Sunshine does not teach or suggest a composition comprising a "penetration enhancer" as such, but Sunshine does teach compositions comprising ibuprofen that are formulated in a sunscreen agent, and includes in its listing of suitable sunscreen agents sunscreens that comprise esters that are useful as penetration enhancers in accordance with the present invention. However, Sunshine does not teach or suggest a composition that becomes touch-dry within three minutes of application, and the teachings of Sunshine in fact lead away from such a composition.

At column 9, lines 18-26, Sunshine sets forth FDA guidelines for sunscreens, stating:

> According to the FDA advisory review panel, "[a]n ideal sunscreen vehicle would be stable, neutral, non-greasy, nondegreasing, nonirritating, nondehydrating, nondrying, odorless, and efficient on all kinds of human skin. It should hold at least 50% water, be easily compounded of known chemicals, and have infinite stability during storage." *Federal Register*, 43, 38218 (1978).

These teachings indicate that the sunscreen-based compositions should comprise at least 50% water, in order to satisfy the cited FDA guidelines. Such a composition, however, would not become touch-dry within three minutes of application. The attached Rule 132 Declaration of Timothy Morgan, a named inventor of the captioned application, evidences that a composition comprising a 50% aqueous ethanol vehicle (e.g., a vehicle comprising 50%

water and 50% ethanol) does not become touch dry within three minutes of application. (This declaration was submitted during prosecution of U.S. Application Serial No. 09/125,436, to which the instant application claims priority.) In view of this evidence, it is apparent that the sunscreen-based compositions suggested by Sunshine, comprising at least 50% water, would not read on the instant claims.

Because the cited references do not make out a prima facie case of obviousness, the instant § 103 rejection is improper and should be withdrawn.

Claims 42-44 and 56-65 are further distinguished over the cited references. These claims recite apparatuses for applying a metered dose, that comprise a metered dose applicator. Although the Office Action asserts that the aerosol dispenser of Knight "delivers a metered dose," this is simply not true.

As used in the art, a "metered dose" refers to a predetermined, measured amount, and a "metered dose applicator" is an applicator that delivers a predetermined, measured amount. There is no teaching or suggestion in Knight of a method of applying a metered dose, let alone of a metered dose applicator. Indeed, the focus of Knight appears to be to provide "a spray unit which will allow a medicament to be applied to any part of the body . . . neatly in a confined area."

Although the Office Action alleges that, "when the pumps of the aerosol and non-aerosol devices are depressed, the device delivers a metered dose of the composition," that allegation is not supported by any evidence of record. To the contrary, because Knight does not teach or suggest that its dispenser provides a metered dose, those skilled in the art will expect that the dose dispensed by Knight's dispenser will vary with the manner in which the device is depressed, *e.g.*, will vary with the magnitude and duration of the depressive force. That Knight's dispenser does not deliver a metered dose is further reflected in its teaching that the hood protects the user's clothing from overspray. *See, e.g.*, '252 patent, column 4, lines 55-59 ("Any overspray in the form of mist or the like created by the unit will be confined within the hood."). A device that is subject to overspray would not be a metered dose applicator.

CONCLUSION

Applicant believes that the present application is in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issue remain, the Examiner is invited to contact the undersigned by telephone in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 CFR § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date November 28, 2006

By _____

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